Sol-Gel Technologies Announces FDA Acceptance for Filing of New Drug Application for Twyneo® for the Treatment of Acne Vulgaris

December 7, 2020

- PDUFA Goal Date Set for August 1, 2021

- Potential to be the first acne treatment that contains a fixed-dose combination of benzoyl peroxide and tretinoin

NESS ZIONA, Israel, Dec. 07, 2020 (GLOBE NEWSWIRE) -- Sol-Gel Technologies, Ltd. (NASDAQ: SLGL), a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases, today announced that its New Drug Application (NDA) for Twyneo® (benzoyl peroxide and tretinoin), an investigational proprietary fixed-dose combination of 3% encapsulated benzoyl peroxide and 0.1% encapsulated tretinoin cream for the treatment of acne vulgaris, has been accepted for filing by the U.S. Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) goal date assigned by the FDA for Twyneo is August 1, 2021.

The NDA filing is based on two positive pivotal Phase 3 randomized, double-blind, multicenter, 12-week, clinical trials that evaluated the safety and efficacy of Twyneo compared to vehicle in patients 9 years of age and older with moderate-to-severe acne vulgaris (N = 858). In both trials, Twyneo demonstrated statistically significant improvement in all co-primary endpoints in the treatment of patients with acne vulgaris of (i) the proportion of patients who succeeded in achieving at least a two grade reduction from baseline and Clear (grade 0) or Almost Clear (grade 1) at Week 12 on a 5-point Investigator Global Assessment (IGA) scale, (ii) an absolute change from baseline in inflammatory lesion count at Week 12 and (iii) an absolute change from baseline in non-inflammatory lesion count at Week 12. The most common adverse events were local reactions, such as pain, dryness, exfoliation, erythema, dermatitis, pruritus and irritation, with nearly all adverse events (AEs) being mild or moderate in severity and no treatment-related serious AEs.

Acne vulgaris is a multifactorial disease that is often treated with a combination of drugs. Twyneo combines two active ingredients that have a complementary mechanism of action in a compelling once-daily treatment.

“This is another important milestone achieved on time by Sol-Gel, in addition to the previous acceptance for filing by the FDA of Epsolay in papulopustular rosacea,” commented Dr. Alon Seri-Levy, Chief Executive Officer of Sol-Gel. “We are proud that by using our proprietary microencapsulation technology we have managed to overcome the instability of tretinoin when combined with benzoyl peroxide. If approved, Twyneo has the potential to provide relief for many of the approximately 40-50 million people in the United States who suffer from acne vulgaris.”

About Sol-Gel Technologies

Sol-Gel is a clinical-stage dermatology company focused on identifying, developing and commercializing branded and generic topical drug products for the treatment of skin diseases. Sol-Gel leverages its proprietary microencapsulation technology platform for the development of Twyneo (benzoyl peroxide and tretinoin) cream, under investigation for the treatment of acne vulgaris, and Epsolay®, under investigation for the treatment of papulopustular rosacea. The Company’s pipeline also includes SGT-210, an early-stage topical epidermal growth factor receptor inhibitor, erlotinib, under investigation for the treatment of palmoplantar keratoderma, and preclinical assets tapinarof and roflumilast. For additional information, please visit www.sol-gel.com.

About Twyneo

Twyneo is an investigational, antibiotic-free, fixed-dose combination of encapsulated benzoyl peroxide, 3%, and encapsulated tretinoin, 0.1%, cream for the treatment of acne vulgaris. If approved, it will be the first acne treatment that contains a fixed-dose combination of benzoyl peroxide and tretinoin, which are separately encapsulated in silica using Sol-Gel’s proprietary microencapsulation technology. Tretinoin and benzoyl peroxide are widely prescribed separately as a combination treatment for acne; however, benzoyl peroxide causes degradation of the tretinoin molecule, thereby potentially reducing its effectiveness if used at the same time or combined in the same formulation. The silica-based microcapsule is designed to protect tretinoin from oxidative decomposition by benzoyl peroxide, thereby enhancing the stability of the active drug ingredients. The silica-based shell is also designed to release the ingredients slowly over time to provide a favorable efficacy and safety profile. Twyneo is not approved by the FDA and the safety and efficacy has not been established.

About Acne Vulgaris

Acne vulgaris is a common multifactorial skin disease that according to the American Academy of Dermatology affects approximately 40 to 50 million people in the United States. The disease occurs most frequently during childhood and adolescence (affecting 80% to 85% of all adolescents) but it may also appear in adults. Acne patients suffer from the appearance of lesions on areas of the body with a large concentration of oil glands, such as the face, chest, neck and back. These lesions can be inflamed (papules, pustules, nodules) or non-inflamed (comedones). Acne can have a profound effect on the quality of life of those suffering from the disease. In addition to carrying a substantial risk of permanent facial scarring, the appearance of lesions may cause psychological strain, social withdrawal and lowered self-esteem.

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the timing of the PDUFA action date for Twyneo and the potential to be the first acne treatment that contains a fixed-dose combination of benzoyl peroxide and tretinoin. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, liquidity, plans and objectives. In some cases, you can identify forward-looking statements by terminology such as “believe,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “expect,” “predict,” “potential,” or the negative of these terms or other similar expressions. Forward-looking statements are based on information we have when those statements are made or our management’s current expectation and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to

the following factors: (i) the adequacy of our financial and other resources, particularly in light of our history of recurring losses and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives; (ii) our ability to complete the development of our product candidates; (iii) our ability to find suitable co-development partners; (iv) our ability to obtain and maintain regulatory approvals for our product candidates in our target markets and the possibility of adverse regulatory or legal actions relating to our product candidates even if regulatory approval is obtained; (v) our ability to commercialize our pharmaceutical product candidates; (vi) our ability to obtain and maintain adequate protection of our intellectual property; (vii) our ability to manufacture our product candidates in commercial quantities, at an adequate quality or at an acceptable cost; (viii) our ability to establish adequate sales, marketing and distribution channels; (ix) acceptance of our product candidates by healthcare professionals and patients; (x) the possibility that we may face third-party claims of intellectual property infringement; (xi) the timing and results of clinical trials that we may conduct or that our competitors and others may conduct relating to our or their products; (xii) intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do; (xiii) potential product liability claims; (xiv) potential adverse federal, state and local government regulation in the United States, Europe or Israel; and (xv) loss or retirement of key executives and research scientists. These and other important factors discussed in the Company's Annual Report on Form 20-F filed with the Securities and Exchange Commission ("SEC") on March 24, 2020 and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. Except as required by law, we undertake no obligation to update publicly any forward-looking statements after the date of this press release to conform these statements.

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